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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No. : 10/661,361 Confirmation No. 6762
Applicant : David A. Mackiewicz, et al.
Filed : September 12, 2003
Art Unit : 3731
Examiner : Elizabeth Houston
Title : RADIOPAQUE MARKERS FOR MEDICAL DEVICES

Docket No.: : ENDOS 64949 (G4164US01)
Customer No. : 24201 January 11, 2010

MAIL STOP APPEAL BRIEF-PATENTS
Commissioner for Patents

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Dear Sir:

I. INTRODUCTION

The present invention relates generally to an implantable medical device, such as a stent, for use or implantation in the body or a body lumen. The implanted medical device includes a structural body made from a superelastic material, such as a nickel-titanium alloy, which attains a certain level of radiopacity. The structural body includes one or more marker holders formed with the structural body. Each marker holder is designed to hold a radiopaque marker which has a level of radiopacity greater than the superelastic material. Each marker holder includes a pair of projecting fingers connected together at a notched region to cooperatively create a V-shaped opening. This V-shaped opening, in turn, is adapted to receive a portion of the radiopaque marker having a V-shape as well. The V-shaped opening formed by the pair of projecting fingers creates a mounting region that allows the projecting fingers to move outwardly, if necessary, in order to receive the V-shaped portion of the radiopaque marker. In this regard, such a mounting structure

allows the marker holder to easily compensate for derivations caused by an imprecise fit between the radiopaque maker and the pair of projecting fingers. A melt or heat weld at the abutment of the radiopaque marker with the projecting fingers securely affixes the components together.

II. NOTICE OF APPEAL

A Notice of Appeal from the final Office Action dated September 10, 2009 is being filed concurrently herewith along with the appropriate fee. A One Month Extension of Time to Respond is also being filed.

III. ISSUES ON APPEAL

At issue is whether claims 1-4, 6, 7, 32, 42, 51 and 52 were improperly rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,741,327 to Frantzen (the "Frantzen patent") in view of DE Patent 19728337 to Ehrfeld (the "Ehrfeld patent").

At issue is whether claims 8-15, 17, 18, 21 and 43-50 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Frantzen patent in view of the Ehrfeld patent and in further view of U.S. Patent No. 6,503,271 to Duerig et al. (the "Duerig patent").

A copy of the pending claims is attached as Exhibit A. A copy of the drawings from the application is attached as Exhibit B. A copy of the final Office Action dated September 10, 2009 is attached as Exhibit C. The Frantzen patent is attached as Exhibit D. The Ehrfeld patent is attached as Exhibit E. The Duerig patent is attached as Exhibit F.

IV. ARGUMENT

A. Rejection of the Claims Based on the Frantzen and Ehrfeld Patent

Claims 1-4, 6, 7, 32, 42, 51 and 52 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Frantzen patent in view of the Ehrfeld patent. Appellant notes that the Examiner acknowledges that the Frantzen patent fails to disclose the use of a marker holder having projecting fingers with a substantially linearly extending contact

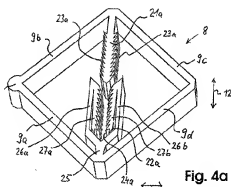
edge, the use of a V-shaped opening or that the radiopaque marker includes a V-shaped mounting area region with linearly extending contact edges. The Examiner relies on the Ehrfeld patent to disclose the shortcomings in the Frantzen patent. However, Appellant strongly disagrees with the Examiner's position for a number of reasons.

First, the Ehrfeld patent appears to be directed to **a mechanism for locking the struts forming the stent body** into an expanded configuration. The Ehrfeld mechanism has nothing to do with attaching separate components to a stent, no less attaching radiopaque markers to a stent. The Frantzen patent teaches the use of radiopaque markers at the ends of a stent in order to increase the overall radiopacity of the stent. The Frantzen patent does not disclose the use of a structure/mechanism for locking the stent body into an expanded position. Therefore, one skilled in the art, in viewing both the Frantzen patent and the Ehrfeld patent, would readily recognize that the locking structure/mechanism of the Ehrfeld patent could possibly be incorporated into the stent disclosed in the Frantzen patent. This feature would allow the stent body of the Frantzen patent to be locked into an expanded position, which is the exact and straightforward teaching of the Ehrfeld patent. The Examiner's position that one skilled in the art would somehow **modify** the Ehrfeld mechanism to now connect radiopaque markers to a stent goes well beyond the teachings of this particular reference.

The composite stent created from the combination of the Frantzen patent with the Ehrfeld patent would include both radiopaque markers located at the ends of the stent, as is disclosed in the Frantzen patent, along with a locking mechanism for maintaining the stent in the expanded position, as is disclosed in the Ehrfeld patent. In regard, the composite stent would enjoy the benefits of the features disclosed in both of these references. However, this composite stent formed from the Frantzen patent and the Ehrfeld patent is not the structure recited in the pending claims. For this reason alone, the combination of the Frantzen patent with the Ehrfeld patent would not create the structure recited in the pending claims. It is submitted that the particular combinations of art

relied on by the Examiner would not have achieved the innovative structure defined in the pending claims.

Even assuming *arguendo* that one skilled in the art would incorporate the connecting technique of Ehrfeld into the stent of Frantzen for the purpose of providing a more secure fit, as suggested by the Examiner, it is noted that the Ehrfeld patent fails to disclose the structure recited in the pending claims. Each of the claims require each projecting finger to have a substantially linearly extending contact edge formed thereon and the radiopaque marker includes a substantially V-shaped mounting region which fits within the V-shaped opening defined by the pair of longitudinally projecting fingers. Each radiopaque marker has a pair of substantially linearly extending contact edges formed thereon each of which contacts a contact edge of the projecting fingers. Therefore, the claims require a structure in which the two projecting fingers define the V-shaped opening. The Ehrfeld patent discloses the use of two projecting fingers. However, the claims further require each projecting finger to have a substantially linearly extending contact edge formed thereon. The Examiner relies on the embodiment of FIG. 4a to support this position. However, as is clear in FIG 4a, reproduced below, the contact edge formed on the fingers of the Ehrfeld fingers is anything but linearly extending.



Rather, the contact edge is a number of zigzag edges which forms V-shaped notches on each finger. This is not the structure recited in the pending claims. Moreover, the Examiner has identified the notches 22a and 24a formed on **each individual projecting finger** as the V-shaped opening. However, the claims do not call for the V-shaped

opening to be formed on each individual projecting finger. This is the structure formed on the Ehrfeld device. Rather, it is the two projecting fingers which define the V-shaped opening. Each projecting finger must have a substantially linearly extending contact edge formed thereon. As can be seen in FIG. 4a above, such a structure is clearly lacking in the Ehrfeld device.

Claims 8-15, 17, 18, 21 and 43-50 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Frantzen patent in view of the Ehrfeld patent and in further view of the Duerig patent. All of these claims have been rejected on the basic combination of the Frantzen patent and the Ehrfeld patent. As addressed above, the combination of the Frantzen patent with the Ehrfeld patent would simply fail to create the basis structure now recited in all of the rejected claims. The secondary reference relied on the Examiner, namely, the Duerig patent, also fail to address the shortcomings of the Frantzen and Ehrfeld combination to achieve the basic structure of the rejected claims. For this reason alone, the combination of references suggested by the Examiner would simply not produce the structure recited in the rejected claims.

V. CONCLUSION

Appellant respectfully requests that the obviousness rejections based on the basis combination of the Frantzen and Ehrfeld patents be withdrawn. The combination of these references fails to create the basic structure recited in all of the pending claims.

Respectfully submitted,
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THM/lm